



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|-----------------|----------------------|---------------------------|--------------------|--|
| 10/659,537 | 09/10/2003 | Deborah Ann Evrard | WYNC-0325 (AM101201NP) | 4846 | |
| 38791 | 7590 07/26/2005 | EXAMINER | | INER | |
| WOODCOCK WASHBURN LLP ONE LIBERTY PLACE - 46TH FLOOR | | | BERNHARD | BERNHARDT, EMILY B | |
| | HIA, PA 19103 | | ART UNIT | PAPER NUMBER | |
| | , | | 1624 | | |
| | | | DATE MAILED: 07/26/2005 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|---|--|-------------------------------------|-------------------------------------|--|--|--|
| Office Action Summary | | 10/659,537 | EVRARD ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Emily Bernhardt | 1624 | | | |
| Period fo | The MAILING DATE of this communication ap or Reply | pears on the cover sheet with the c | orrespondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)🖂 | Responsive to communication(s) filed on 05 M | <u>May 2005</u> . | · | | | |
| | | is action is non-final. | | | | |
| 3) | | | | | | |
| | closed in accordance with the practice under | Ex parte Quayle, 1935 C.D. 11, 45 | 53 O.G. 213. | | | |
| Dispositi | on of Claims | • | | | | |
| 4)⊠ | Claim(s) 1-52 is/are pending in the application | n. | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| | Claim(s) is/are allowed. | | | | | |
| 6)⊠ | Claim(s) 1-10 and 49-52 is/are rejected. | | | | | |
| | Claim(s) 11-48 is/are objected to. | | | | | |
| 8)□ | Claim(s) are subject to restriction and/o | or election requirement. | | | | |
| Applicati | on Papers | | • | | | |
| 9)[| The specification is objected to by the Examin | er. | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| | Applicant may not request that any objection to the | | | | | |
| | Replacement drawing sheet(s) including the correct | | | | | |
| 11) | The oath or declaration is objected to by the E | xaminer. Note the attached Office | Action or form PTO-152. | | | |
| Priority u | ınder 35 U.S.C. § 119 | <u>.</u> | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice | e of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | |
| 2) 🔲 Notice 3) 🔯 Inform | e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) · No(s)/Mail Date <u>5/6/05</u> . | Paper No(s)/Mail Da | ate Patent Application (PTO-152) | | | |

Art Unit: 1624

In view of applicants' response filed 5/5/05 the following applies.

Claims 1-4,6-10 and 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Insertion of "dihydrobenzodioxinyl" as a choice for "Ar" in the generic claims lacks descriptive support in the disclosure as originally filed. While the species in claim 17 has the ring system, said species alone cannot support the genus reciting varying values for remaining variables. Note Ex parte Winters 11 USPQ2d 1387 regarding reliance on a species to create a generic concept. Also see Tronzo v. Biomet 47 USPQ2d 1829.

Claims 1-5,7-10 and 49-52 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection remains notwithstanding applicants' traverse. Simply asserting that the entire genus has

Art Unit: 1624

SSRI/5HT1A activity does not automatically avoid an enablement rejection. If it did, the factors discussed in In re Wands and the MPEP would not have to be evaluated. Given the many factors that do pertain in the instant case as discussed in previous actions there is reason to question efficacy of the instant scope given the wide variation in activity with respect to SSRI and 5HT1A just in replacing substituents on phenyl rings in compounds having the same X-Y core. Applicants' analysis of the enablement requirement is not consistent with the MPEP, namely 2164.05(a) which emphasizes that the state of the prior art can be relied on to contribute to an enablement issue while the absence thereof necessarily would not. The relevant case law is not Armbruster Atlas Powder which dealt with an art area other than pharmaceuticals but rather Surrey previously cited as well as In re Fisher 166 USPQ 18 which emphasized that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved".

Claim 49 also remains rejected under par.one for reasons set forth in the previous action- see pages 4 and 5. The references previously provided do not evidence that SSRI's or 5-HT1A antagonists are known for such a range of uses at the time of applicants' effective filing date. Applicants do nor address much less refute these references.

Art Unit: 1624

Claims 11 –48 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants' IDS filed 5/6/05 has been noted but none of the cited documents which are voluminous extracts from textbooks appear remotely relevant. If applicants disagree they should point to the relevant portions.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1624

Page 5

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Emily Bernhardt
Primary Examiner
Art Unit 1624